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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/753,313 12/29/00 CHOI

P PROTEO.P16

EXAMINER

HM22/0824

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JIANG, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

08/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<p align="center">Office Action Summary</p>	<p>Application No.</p> <p>09/753,313</p>	<p>Applicant(s)</p> <p>CHOI ET AL.</p>	
	<p>Examiner</p> <p>Shaojia A. Jiang</p>	<p>Art Unit</p> <p>1617</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application claims priority to provisional application Serial No. 60/173,959.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for standardized green tea extract (e.g., 50% polyphenols) disclosed in the specification (see, e.g., page 2 line 17 and Examples 1-2), does not reasonably provide enablement for any green tea, green tea leaves, or green tea derivatives, such as catechins, bioflavonoids, flavanols, flavandiols, tannins or derivatives, OR a plant of the genus *Camellia*, species *sinensis*, OR the family Theaceae. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicant's claims encompass the employment of any compound which may be termed "green tea derivatives" or "a plant of the genus *Camellia*, species *sinensis*" or "the family Theaceae".

Applicant's specification provides examples merely showing how "standardized green tea extract" may be employed in the pharmaceutical composition useful herein to treat the claimed diseases. See Examples 1-2 pages 29-34. The specification contains no working examples or guidance showing how any further green tea derivatives may

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be employed in the claimed methods. Since any significant structural variation to a compound would be reasonably expected to alter its properties, one of ordinary skill would be required to perform undue experimentation to determine which, if any, other compounds termed "green tea derivatives" or "a plant of the genus *Camellia*, species *sinensis*" or "the family Theaceae" would be useful in the claimed method to treat amyloidosis.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression " standardized green tea extract" in claims 1 and 11 renders the claim indefinite. The expression " standardized green tea extract" is not defined by the claim. Each claim must be self-contained. The expression "standardized green tea extract " is unclear as to the composition encompassed thereby and what the standardized green tea extract herein is.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and

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Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 2, 8, 18, and 19 recite the broad recitation "amyloidosis or prion diseases" and the claim also recites "associated.. or including... or related...." which is the narrower statement of the range/limitation.

Regarding claims 2 and 8 the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The expressions "type" and "various forms" in claims 1 and 8 render claims 1-3 and 8-9 indefinite. The expressions "type" and "various forms" are not defined in the claim. The scope of the claim is unclear as to as to the method encompassed thereby.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Castillo et al. (N, PTO-892).

Castillo et al. discloses that plant matter such as the known major active ingredient of standardized green tea leaf extract, polyphenols, and Cat's claw (the inner bark and root parts of *Uncaria tomentosa* plant), within the instant claims, are useful in methods of treatment, prevention, or management of an amyloidosis or amyloid formation, deposition, accumulation in a mammal. See abstract, pages 1-3 specially page 2 lines 23-24, page 3 lines 21-23 and 31-33, page 6 lines 30-31, page 9 lines 12-14, page 12 lines 12-14, and claim 6. Thus, Castillo et al. anticipates claims 1-4 and 10-11.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10245342 (O, PTO-892).

JP 10245342 discloses that a polyphenol (known major active ingredient of standardized green tea leaf extract) is useful for reducing an amyloidosis or amyloid formation, deposition, accumulation in a mammal. See abstract. JP 10245342's teaching is inherent in the instant claimed methods of treatment, prevention, or management of an amyloidosis or amyloid formation, deposition, accumulation in a mammal. See *Ex parte Novitski*, 26 USPQ 2d 1389. Thus, JP 10245342 anticipates claims 1-4.

Claims 1-9 and 11-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Schultes R.E. (U, PTO-892).

Schultes teaches that the plants such as teas of the leaves or roots are useful for treating Alzheimer's disease in a mammal. It is well known that tea plants such as green teas contain active ingredients herein such as catechins and polyphenols. It is also well known that *Camellia sinensis* of the family Theaceae is a green tea plant. See abstract. Schultes's teaching is inherent in the instant claimed methods of treatment, prevention, or management of an amyloidosis or amyloid formation, deposition, accumulation such as Alzheimer's disease in a mammal. See *Ex parte Novitski*, 26 USPQ 2d 1389. Thus, Schultes anticipates claims 1-9 and 11-12.

Claims 1-9 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Shin-Ya et al., (V, PTO-892).

Shin-Ya et al. teaches that catechin, a known ingredient of green tea, black tea, or other natural sources is useful for against beta-amyloid toxicity in a mammal. See abstract. Shin-Ya's teaching is inherent in the instant claimed methods of treatment, prevention, or management of an amyloidosis or amyloid formation, deposition, accumulation such as Alzheimer's disease in a mammal. See *Ex parte Novitski*, 26 USPQ 2d 1389. Thus, Shin-Ya et al. anticipates claims 1-9 and 11-12.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
August 15, 2001


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